

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PATRICIA HOSBROOK,	:	
Plaintiff,	:	
v.	:	Case No. 3:20-cv-88
ETHICON, INC., et al.,	:	JUDGE WALTER H. RICE
Defendants.	:	

DECISION AND ENTRY OVERRULING IN PART, OVERRULING AS
MOOT IN PART AND SUSTAINING IN PART PLAINTIFF'S MOTIONS
IN LIMINE (DOC. ##130, 131, 132, 133 AND 134); AND SUSTAINING
PLAINTIFF'S MOTION TO APPLY NEW JERSEY LAW ON PUNITIVE
DAMAGE CLAIM (DOC. #135)

Before the Court are five motions filed by Plaintiff, Patricia Hosbrook ("Plaintiff"), Doc. ##130, 131, 132, 133 and 134, to exclude the trial testimony of certain expert witnesses identified by Defendants, Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon" or "Defendants"). Defendants have filed responses, Doc. ##136, 138, 142, 143 and 140, respectively. Following oral argument held September 17, 2021, Plaintiff filed a Notice of Supplemental Authority. Doc. #180. Plaintiff has also filed a Motion to Apply New Jersey Law on Plaintiff's Punitive Damage Claim, Doc. #135, and Defendants have filed a response. Doc. #137. For the reasons set forth below, Plaintiff's Motions in Limine are overruled in part, overruled as moot in part and sustained in part.

Plaintiff's Motion to apply New Jersey Law to her punitive damages claim is sustained.

I. Procedural and Case Background

Ethicon, a subsidiary of Johnson & Johnson, designed and manufactured Prolift, a mesh product used to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). On March 27, 2007, the Prolift was surgically implanted in Plaintiff in Livingston, Tennessee, and on May 14, 2012, she underwent surgery in Dayton, Ohio, for the "excision of extruded vaginal mesh and rectocele repair." Doc. #33-1. On November 16, 2012, Plaintiff filed a "Short Form Complaint" against Defendants in certain multidistrict litigation pending in the United States District Court for the Southern District of West Virginia entitled "*In re Ethicon Inc., Pelvic Repair System Products Liability Litigation, MDL No. 2327.*" Doc. #1.¹ Her case was remanded to this Court's docket on March 9, 2020, for trial.

On April 23, 2021, the Court sustained Defendants' Motion for Partial Summary Judgment. Doc. #120. As a result of this Decision and Entry, Plaintiff's

¹ In the Ethicon Pelvic MDL, the cases were divided into "waves" with this case included in the "Ethicon Wave 5 cases." Doc. #20. Judge Goodwin of the MDL Court ruled on all pretrial matters in the waves, including discovery and evidentiary issues. Here, the Court will adopt all of the MDL opinions unless it determines that "extraordinary circumstances" exist. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) ("courts should be loathe" to "revisit prior decisions of its own or a coordinate court in the absence of extraordinary circumstances"); *Hanover Ins. Co. v. Am. Eng'g Co.*, 105 F.3d 306, 312 (6th Cir. 1997).

sole claim is for design defect under Tennessee law, as codified in the Tennessee Products Liability Act of 1978, Tennessee Code Annotated§ 29-28-101, et seq. ("TPLA"). Doc. #120.²

II. Standard of Review

Fed. R. Evid. 702, governing expert witness testimony, provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court held that the trial judge must act as a gatekeeper, excluding expert witness testimony that is not both relevant and reliable. *Id.* at 589. Relevant testimony is that which has a “tendency to make the existence of any fact that is

² The Court also sustained in part and overruled in part Defendants' Motion to Dismiss the Case-Specific Opinions of Bruce Rosenzweig, M.D. Doc. #120.

of consequence to the determination of the action more probable or less probable than it would be without the evidence.” Fed. R. Civ. P. 401.

Expert witness testimony must also rest on a reliable foundation. *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 529-30 (6th Cir. 2008). Reliable evidence is “supported by appropriate validation.” *Daubert*, 509 U.S. at 590. In determining whether expert witness testimony is sufficiently reliable, the court must focus “on [the] principles and methodology, not on the conclusions they generate.” *Id.* at 595. Factors to be considered include “testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique’s operation, and general acceptance in the relevant scientific community.” *United States v. Langan*, 263 F.3d 613, 621 (6th Cir. 2001) (citing *Daubert*, 509 U.S. at 593–94).

When a party moves to exclude expert witness testimony, an evidentiary hearing is not necessarily required. *Greenwell v. Boatwright*, 184 F.3d 492, 498 (6th Cir. 1999).

III. Plaintiff’s Motion to Exclude the General Opinion Testimony of Elaine Duncan – Doc. #130

Plaintiff seeks to exclude the expert testimony of Defendants’ expert witness, Elaine Duncan. Defendants have withdrawn this expert designation. Doc. #136. Accordingly, Plaintiff’s Motion to Exclude the General Opinion Testimony of Elaine Duncan, Doc. #131, is OVERRULED as moot.

IV. Plaintiff's Motion to Exclude the General Opinion Testimony of Gregory T. Bales, M.D. – Doc. #131

Plaintiff moves to exclude the “general opinion testimony” of Dr. Gregory Bales pursuant to Fed. R. Evid. 702. She has refiled a motion concerning this witness that was originally filed in Wave 1 on April 21, 2016. The MDL Court entered an order rejecting each of the challenges raised. *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493660 (S.D.W. Va. Aug. 25, 2016), Doc. #138-1.

The plaintiffs in Wave 5 of the MDL, which included Plaintiff herein, filed a Notice of Adoption, and incorporated the Wave 1 Motion to Exclude Dr. Bales. The MDL Court addressed the Wave 5 Plaintiffs’ arguments, rejected same, and adopted its Wave 1 Order entering it in the Wave 5 cases. *Id.*, PageID#29149.

Defendants argue in their response, Doc. #138, “[U]nder the doctrine of the law of the case, a decision on an issue made by a court at one stage of a case should be given effect in successive stages of the same litigation.” *United States v. Todd*, 920 F.2d 399, 403 (6th Cir. 1990). They further add, “[A]s a court in this district recognized [Rice, J.], an MDL Court’s prior rulings constitute law of the case upon remand. *See Bowles v. Novartis Pharm. Corp.*, No. 3:12-cv-145, 2013 WL 5297257, at *5 n.1 (S.D. Ohio Sep. 19, 2013) (The MDL Court’s ruling constitutes the ‘law of the case.’”).”

At the September 17, 2021, oral argument Plaintiff agreed that the law of the case applies and that her motion is moot.

Accordingly, the Court finds that based on the law of the case doctrine, Plaintiff's Motion to Exclude the General Opinion Testimony of Dr. Gregory T. Bales, M.D. is OVERRULED as moot.

**V. Plaintiff's Motion to Exclude the General Opinion Testimony
Shelby Thames, PhD. – Doc. #132**

Plaintiff moves to exclude Dr. Thames pursuant to Fed. R. Evid. 702, 403 and 104. The MDL plaintiffs filed a Motion to Exclude Dr. Thames in Wave 1 of the MDL which the MDL Court addressed and resolved. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4608160, at *2–4 (S.D.W. Va. Sept. 2, 2016), Doc. #142-1, PageID#29211. The plaintiffs in Wave 5 of the MDL, which included Plaintiff herein, filed a Notice of Adoption which incorporated the Wave 1 briefing, and the MDL Court addressed the Wave 5 Plaintiffs' arguments, rejected same and adopted its Wave 1 Order and entering it in the Wave 5 cases. *See*, "Wave 5 Order Adopting Mem. Op. and Order (*Daubert* Ruling re: Shelby Thames, Ph.D.) (July 27, 2018) Doc. #142-1, Doc. #142-1, PageID#29206.

Defendants argue that the doctrine of the law of the case applies and that Plaintiff's motion should be overruled as a result of the MDL Court's ruling. At the September 17, 2021, oral argument, Plaintiff agreed that her motion was moot.

Accordingly, the Court finds that based on the law of the case doctrine, Plaintiff's Motion to Exclude the General Opinion Testimony of Shelby Thames, PhD., is OVERRULED as moot.

VI. Plaintiff's Motion to Exclude the General Opinion Testimony of Steven Goldwasser, M.D. - Doc. #133

Plaintiff moves to exclude the "general opinion testimony" of Dr. Steven Goldwasser pursuant to Fed. R. Evid. 702, 403 and 104. Plaintiff's motion to exclude testimony of this witness was originally filed in Wave 4 of the MDL cases. An Opinion and Order was issued by Judge Goodwin on July 24, 2018, in the Wave 4 cases. Doc. #143-1, PageID#29231. The Plaintiffs in Wave 5, including Plaintiff herein, filed a Notice of Adoption, Doc. #143-3, PageID#29349, of the Wave 4 motion to exclude Dr. Goldwasser. On July 26, 2018, the MDL Court ordered that the "Memorandum Opinion and Order (Daubert Motion re: Steven Goldwasser, M.D.) . . . entered on July 24, 2018, as to the Ethicon Wave 4 cases is ADOPTED in the Wave 5 cases." Doc. #52. As a result of Judge Goodwin's rulings, Dr. Goldwasser was excluded from testifying about "what information should or should not be included in the IFU" (instructions for use), although he could testify about "the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *Id.*, PageID#286. Additionally, the MDL Court determined that Dr. Goldwasser could testify regarding degradation finding that his "extensive clinical experience, combined with his review of peer reviewed

literature, qualifies Dr. Goldwasser to opine on mesh's reaction to and effect on the human body." Doc. #52, PageID#287.

Two issues were unresolved in the MDL Court's Opinion and Order of July 24, 2018, adopted on July 26, 2018, in the Wave 5 cases: (1) whether Dr. Goldwasser "may testify about whether certain risks were common knowledge" among pelvic floor surgeons, Doc. #52, PageID#286, and (2) whether he may testify relating to a "vaginal prolapse database" that he "maintains with a urologist colleague at the University of Florida." *Id.*, PageID#287.

Defendants argue that based on Dr. Goldwasser's extensive clinical experience and his review of the medical literature, he should be permitted to testify as to "commonly known risks" that "have been discussed in medical literature discussing pelvic floor surgeries for decades." However, because the Court has previously ruled that Plaintiff has no claim under Tennessee law based on the failure to warn, testimony from Dr. Goldwasser relating to what the known risks among pelvic floor surgeons were in the medical literature is irrelevant to the issue of whether the Prolift was defectively designed under Tennessee law.

As to Dr. Goldwasser's vaginal prolapse database, in the Wave 4 ruling issued by the MDL Court, Judge Goodwin stated it would not exclude Dr. Goldwasser's testimony on the database, because the MDL Court had "limited information regarding the methodology employed by Dr. Goldwasser and his colleague in maintaining this database." As such, he reserved ruling on this issue until trial. The Court notes that Plaintiff has not supplemented her argument since

the MDL Court's July 24, 2018, ruling and, as a result, the Court has no more information on this subject than that provided to Judge Goodwin.

Accordingly, Plaintiff's Motion to Exclude the General Opinion Testimony of Dr. Goldwasser is SUSTAINED in part and OVERRULED in part. Based on the law of the case doctrine, the Court SUSTAINS the exclusion of Dr. Goldwasser's testimony about what information should or should not be included in an IFU, and OVERRULES Plaintiff's motion to exclude testimony from Dr. Goldwasser regarding degradation. Because Plaintiff has no claim under Tennessee law based on failure to warn, the Court SUSTAINS the exclusion of any testimony from Dr. Goldwasser regarding whether certain risks were common knowledge to pelvic floor surgeons based on the medical literature. The Court OVERRULES, without prejudice to renewal at trial, testimony concerning Dr. Goldwasser's vaginal prolapse database. Until the Court hears more evidence, neither party may refer to Dr. Goldwasser's database in either *voir dire* or opening statement. If counsel for Plaintiff and/or Defendants wishes to introduce evidence concerning this subject, this motion can be argued to the Court outside of the presence of the jury.

VII. Motion to Exclude the General Opinion Testimony of Timothy Ulatowski – Doc. #134

Plaintiff moves to exclude the general opinion testimony of Timothy Ulatowski. Defendants respond that based on the law of the case doctrine, *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493646,

at *2 (S.D.W. Va. Aug. 25, 2016), the MDL Court's position regarding the FDA's 510(k) clearance process, as well as the FDA's labeling and adverse event reporting regulations, Mr. Ulatowski will not offer any opinions in this case.

Accordingly, the Court **OVERRULES** Plaintiff's Motion to Exclude the General Opinion Testimony of Timothy Ulatowski as moot.

VIII. Plaintiff's Motion to Apply New Jersey Law on her Punitive Damage Claim – Doc. #135

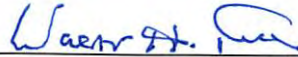
Plaintiff moves the Court for an order applying New Jersey law on her punitive damage claim. Defendants do not oppose this motion.

Accordingly, Plaintiff's Motion to Apply New Jersey Law on her Punitive damage claim is **OVERRULED** as moot.

IX. Conclusion

For the reasons set forth above, Plaintiff's motions, Doc. ##130, 131, 132, 133 and 134, seeking to exclude the trial testimony of certain expert witnesses identified by Defendants, pursuant or Fed. R. Evid. 702 and *Daubert*, are **OVERRULED** in part, **OVERRULED** as moot in part and **SUSTAINED** in part. Plaintiff's Motion to Apply New Jersey Law on her Punitive Damage Claim, Doc. #135, is **SUSTAINED**.

Date: January 11, 2022



WALTER H. RICE
UNITED STATES DISTRICT JUDGE